

## REMARKS

By way of summary, Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 were previously pending in the above-identified application. Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 remain as previously presented.

**A. Response to Rejections of Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 under 35 U.S.C. § 103**

Claims 25, 27, 28, 60, 62, 63 and 83-89 were rejected as obvious over U.S. Pub. No. 2001/0012950 by Nishtala et al. ("Nishtala") in view of U.S. Pat. No. 5,185,545 to Trudell and U.S. Pat. No. 6,808,520 to Fourkas et al. ("Fourkas"). Claims 47, 49, 50, 72, 74 and 75 were rejected as being unpatentable over Nishtala in view of Trudell, Fourkas and U.S. Pat. No. 5,961,499 to Bonutti et al. ("Bonutti"). Applicants respectfully disagree and traverse these rejections, the characterization of the pending claims, and each and every implicit and explicit official notice.

**1. Independent Claim 25**

Claim 25 recites, and Nishtala, either alone or in combination with Trudell and Fourkas, fails to disclose, *inter alia*, "a circumferentially continuous elongate tubular structure," "a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile," and "inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile."

The Office Action acknowledged that Nishtala fails to disclose "the distal region having a first, folded, smaller cross-sectional profile and longitudinal creases [and] ... releasing the elongate tubular structure from a constraining tubular jacket [and] ... tearing said tubular jacket along a perforation" and relied on Trudell and Fourkas as teaching these features.

Specifically, the Office Action points to Trudell as disclosing tearing a tubular constraining jacket along a deformation and points to Fourkas as disclosing a folded distal region. The Office Action then states that it would have been obvious to modify the method of Nishtala to include the distal folded region and the constraining tubular jacket as recited in the pending claims.

However, Nishtala is directed to a “single integrated device that can reach any of a plurality of expanded diameters upon actuation by a user of an actuating mechanism which directs and controls the dilation of a dilating element.” Nishtala Abstract. Nishtala further describes the objective of its device as “dial-a-size functionality integrated into a single device.” Nishtala Spec. ¶ [0010]. It is unclear and non-obvious how this “dial-a-size” function could be used in conjunction with a “circumferentially continuous,” folded sheath. For instance, it is unclear how to dial a fold to a plurality of diameters in a controlled manner, since, for example, it would be necessary to precisely control the distance of each crease of the fold from the center of the device. Accordingly, even assuming, *arguendo*, that Fourkas and/or Trudell disclose a folded sheath, the proposed combination of Nishtala and Fourkas and/or Trudell would require undue experimentation or “render Nishtala “unsatisfactory for its intended purpose.” M.P.E.P. § 2143.01(V).

Moreover, because Nishtala is directed single integrated device that can reach any of a plurality of expanded diameters upon actuation by a user of an actuating mechanism which directs and controls the dilation of a dilating element modifying such a device to include a constraining jacket would be redundant and thus there is no modification to combine such discloses as suggested in the Office Action.

For at least the reasons expressed above, Applicants respectfully request that the rejection of Claim 25 be withdrawn and that this claim be passed to allowance.

## **2. Independent Claim 47**

Claim 47 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua, Trudell, and Bonutti fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and a beveled distal tip,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.”

For at least the reasons expressed above, Applicants respectfully request that the rejection of Claim 47 be withdrawn and that this claim be passed to allowance.

**3. Independent Claim 60**

Claim 60 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua and Trudell, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 60 be withdrawn and that this claim be passed to allowance.

**4. Independent Claim 72**

Claim 72 recites and, for at least similar reasons as expressed above in relation to Claims 25 and 47, Nishtala, either alone or in combination with Trudell, Fourkas, and Bonutti, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, smaller cross-sectional profile and a beveled distal tip,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 72 be withdrawn and that this claim be passed to allowance.

**5. Independent Claim 87**

Claim 87 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Trudell and Fourkas, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region, the distal region having a first, folded, substantially continuous, smaller cross-sectional profile” and “inflating a balloon positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, folded, substantially continuous, smaller cross-

sectional profile to said second, unfolded, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 87 be withdrawn and that this claim be passed to allowance.

**6. Dependent Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89**

Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 each depend directly from one of independent Claims 25, 47, 60, 72 and 87. They are each believed to be patentably distinguished, *inter alia*, for the reasons set forth above in relation to the independent claim from which each depends and for the additional features recited therein. Accordingly, Applicants respectfully request that the rejections of Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 be withdrawn and that these claims be passed to allowance.

**B. No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

**Application No.:** 10/728,728  
**Filing Date:** December 5, 2003

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 4-29-2011

By: /Rabinder N. Narula/  
Rabinder N. Narula  
Registration No. 53,371  
Attorney of Record  
Customer No. 20995  
(949) 760-0404

9451795  
11154589  
042911